JUL 14 2011

510(K) Summary

Submitter
Dynamic Innovations Inc.
Kelvin Yoo
5023 North Parkway Calabasas,
Calabasas, CA 91302
Email: Kelviny@diilv.com
Tel. 888) 446 – 9995
Fax. 310) 356 – 3183

Official Correspondent
Kodent Inc.
April Lee
325 N. Puente st. Unit B
Brea, CA 92821
Email: kodentinc@gmail.com
Phone: 714-525-0114
Fax: 714-525-01116

Device Information

- Trade Name: OsseoFuse Dental Implant System
- Common Name: Endosseous dental implant
- Classification Name: Implant, Endosseous, Root-Form
- Product Code: DZE
- Regulation Number: 872.3640
- Device Class: Class II
- Date of submission: 1/19/11

General Description

The OsseoFuse Dental Implant system includes Hexa-Plus fixture, Hexa-Plus abutment, and Lab components. This system made of Titanium intended to be surgically placed in the bone of the upper or lower jaw arches for loading after a conventional healing period. Implants may be used to replace one or more missing teeth. It is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface of this system has been treated with R.B.M.

Hex-Plus Fixture is only part to be implanted into bone, and to provide connection of prosthetic devices or other components of a dental implant set with human body (mandibular or maxillary bone). Surface of part to be implanted into bone is treated by RBM (Resorbable Blast Media) method to increase junction strength by increasing the area of bone-implant interface.

The tight and precisely fitting implant-abutment relation of the internal hexagon with internal bevel design makes abutment connection a quick and simple procedure.

Indication for Use

The OsseoFuse Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained,

or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

- RENOVA™ Internal Hex Implant System (Lifecore Biomedical, Inc.; K032774)
- BioHorizons Internal Implant System (Abutments) (BioHorizons Implant System, Inc.; K071638)
- Zimmer Dental Implant System (Abutments) (Zimmer Dental, Inc. ;K061410)

Comparison to Predicate Devices:

1) RENOVA™ Internal Hex Implant System

The OsseoFuse Dental Implant system has a substantially equivalent intended use as the identified predicates (K032774). This dental implant system made of titanium and the surface has been treated with RBM. It is intended to be surgically placed in the bone of the upper or lower jaw arches. The system is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics.

The OsseoFuse Dental Implant systems are similar in fundamental scientific technology to the predicate devices (K032774) in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutment. The subject and predicate devices are similar in size, materials, surface treatment, and are sterilized via gamma irradiation. The OsseoFuse Dental Implant system and the predicates include instruments to assist with the implant procedure.

2) BioHorizons Internal Implant System (Abutments)

The OsseoFuse Dental Implant system (Abutments) has a substantially equivalent as the identified predicate (K071638) especially in size, materials, and surface treatment.

3) Zimmer Dental Implant System (Angled Abutment)

The OsseoFuse Dental Implant system (Angled Abutment) has substantially equivalent as the identified predicate (K061410) especially in size, materials, and angulations.

Substantial Equivalence Comparison chart

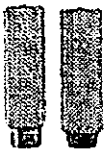
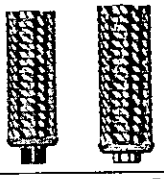
- RENOVA™ Internal Hex Implant System (Fixture & Abutments)

	Subject Device	Predicate Device
510(K) Number	N / A	K032774
Device Name	OsseoFuse Dental Implant System	RENOVA™ Internal Hex Implant System
Manufacturer	KJ Meditech Co., Ltd.	Lifecore Biomedical, Inc.
Indications for Use	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.	Intended for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cement-retained, screw-retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
Design	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with micro-thread provides crestal seal. • 1mm smooth titanium surface allows soft tissue maintenance. • Body Design: Tapered design enables placement near impringing anatomical structures while maximizing prosthetic table diameter for natural emergence profile.	• Implant Type: Bone Level Implant • Connection Type: Internal Hexagon • Neck Design: Straight walled neck with circumferential thread provides crestal seal. • 1mm smooth titanium surface allows soft tissue maintenance. • Body Design: Tapered design enables placement near impringing anatomical structures while maximizing prosthetic table diameter for natural emergence profile.
Fixture		
	3.75mm, 4.1mm, 4.5mm, 5.25mm	3.75mm, 4.5mm, 4.75 mm
	8.5 – 16.0 mm	8.5 – 16.0 mm

Healing Abutment		
	4.0mm, 4.7mm, 5.5mm	4.5mm, 4.75mm
	3mm, 5mm, 7mm	1.5mm, 3mm, 5mm
Ball Abutment		
	3.58mm	3.75mm, 4.5mm, 4.75mm
	3mm	1mm, 2mm, 3mm, 4mm
Abutment Screw		
	1.25mmD Hex	1.25mmD Hex
Endosseous Implant Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23
Surface Treatment	RBM Treatment on the fixture body	RBM Treatment on the fixture body
Implant Sterile	Yes	Yes
Sterilization Method	Gamma	Gamma

- BioHorizons Internal Implant System (Abutments)

	Subject Device	Predicate Device
510(K) Number	N / A	K071638
Device Name	OsseoFuse Dental Implant System	BioHorizons Tapered Internal Implant System
Manufacturer	KJ Meditech Co., Ltd.	BioHorizons Implant System, Inc.
One-Step Abutment		
	4.5mm, 5.25mm, 6.0mm	3.5mm, 4.5mm, 5.7mm
	7.95mm, 1.62mm	8mm , 1.5mm
	-	TiN coating
Final Cement Abutment		
	4.5mm, 5.25mm, 6.0mm	4.5mm
	12.27mm, 2mm	10mm, 2mm
	TiN coating	TiN coating

Straight Abutment		
	3.75mm	3.5mm, 4.5mm, 5.7mm
	12mm	10mm
	TiN coating	TiN coating
Temporary Abutment		
	4.75mm	3.5mm, 4.5mm, 5.7mm
	11.45mm	10mm
	-	-
Endosseous Implant Abutment Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23

- Zimmer Dental Implant System (Angled Abutment)

	Subject Device	Predicate Device
510(K) Number	N / A	K061410
Device Name	OsseoFuse Dental Implant System	Zimmer Dental Implant System
Manufacturer	KJ Meditech Co., Ltd.	Zimmer Dental, Inc.
Appearance		
Diameter	5.25mm	5.25mm
Length	11.40mm	11.40mm
Angulation	17°	20°
Surface treatment	TiN coating	-
Endosseous Implant Abutment Material	Ti 6Al 4V ELI, Gr.23	Ti 6Al 4V ELI, Gr.23

Safety and Effectiveness

OsseoFuse Dental Implant System is substantially equivalent to predicate devices when the devices have the same intended use and the same technological characteristics as the previously cleared predicate devices, and it can be demonstrated that the devices are as safe and effective as the predicate devices, and that the new device does not raise different questions regarding safety and effectiveness as compared to the predicate devices. The OsseoFuse Dental Implant System, as designed and manufactured, is as safe and effective as the predicate devices and therefore is determined to be substantially equivalent to the referenced predicate devices.

Performance Data:

All of the data consistent with the recommendations in the FDA guidance document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, May 12, 2004, mechanical testing of the implants demonstrated that the OsseoFuse Dental Implant System possess mechanical strength at least equivalent to the predicate devices.

Among the information and data presented in this 510(k) submission to support the substantial equivalence of the OsseoFuse Dental Implant System to the specified predicate devices, fatigue testing demonstrated that there is substantial equivalence in the performance, safety and effectiveness between the OsseoFuse Dental Implant System and the referenced predicate devices. Fatigue testing also demonstrated that this system meets its predefined acceptance criteria and performs in accordance with its intended use.

Conclusion

The OsseoFuse Dental Implant System, subject of this submission, constitutes a safe, reliable and effective medical device, meeting all the declared requirements of its intended use. Device presents no adverse health effects or risks cannot be substantiated. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, OsseoFuse Dental Implant System and its predicate devices are believed to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Dynamics Innovations Incoporated
C/O Ms. April Lee
Consultant
Kodent Incorporated
325 North Puente Street, Unit B
Brea, California 92821

JUL 14 2011

Re: K110577
Trade/Device Name: OsseoFuse Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: June 17, 2011
Received: June 27, 2011

Dear Ms. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/Centers Offices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(K) Number (if known): K110577

Device Name: OsseoFuse Dental Implant System

Indication for Use:

The OsseoFuse Dental Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework. This system is dedicated for one and two stage surgical procedures and not dedicated for immediate loading. This system is intended for delayed loading.

Prescription Use ____X_____ AND/OR Over-The-Counter _____

(Part 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110577